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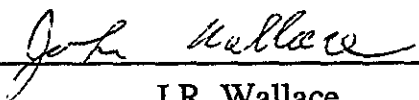
ENVIRONMENTAL TECHNOLOGY SECTOR  
QUALITY ASSURANCE PROGRAM PLAN

SSS-R-81-4163

D. Masunaga  
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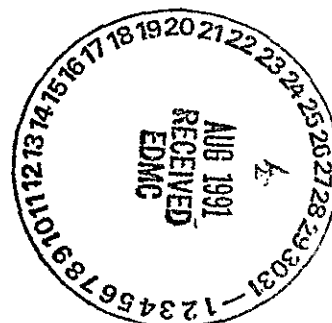
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Approved:

  
J.R. Wallace

JULY 2, 1990

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July 2, 1990



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## 1.0 INTRODUCTION

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This document details the S-CUBED Quality Assurance Program Plan. The level of quality assurance applied to a specific project conducted by S-CUBED depends on the project objectives and the end uses of the data generated. The S-CUBED program is designed to be flexible, and to ensure that the data are of sufficient and appropriate quality to fulfill specific research or technical services support project requirements. It is essential that these data are complete, representative, comparable, valid, of known precision and accuracy, and legally defensible. The establishment of Quality Assurance (QA) protocols makes possible acceptable data quality through the use of planned systematic methods and activities applicable to all S-CUBED efforts.

Quality assurance, therefore, represents the total integrated program for assuring the reliability of monitoring and measurement data. Assurance of this reliability is, in turn, maintained through the use of discrete quality control (QC) functions which involve the routine application of detailed procedures for measuring and achieving the desired level of performance. QA at S-CUBED is a system of activities that provides confidence that an overall quality control effort is being performed effectively.

The general objective of the S-CUBED QA Program is that all data be of known and adequate quality, consistent with project objectives. This objective translates into requirements for facilities and equipment, methodology, reagents and supplies, personnel, data review and reporting, archiving, and specific QC procedures carried out in conjunction with each sampling and analytical activity.

Activities and policies of the S-CUBED QA Program fall into three major areas:

- (I) Planning for Quality Assurance
- (II) Quality Assurance Assistance
- (III) Quality Assurance Auditing

S-CUBED policies for each of the above three program areas are discussed below.

The S-CUBED QA Program Plan requires adequate planning for quality assurance on all projects involving sampling and analysis. Among other things, this requirement means that chemical analyses can proceed only after the type and frequency of quality control samples have been specified, along with acceptance criteria and corrective action. When specified by contract (e.g., EPA Projects) or otherwise required by S-CUBED management, a QA Project Plan will be prepared. The QA Project Plan is described in Section 6.1 of this document. The Project Manager is responsible for review and

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approval of the Project Plan, but may request the Quality Assurance Manager (QAM) or others to assist in the review.

The S-CUBED QA Program Plan requires that the Quality Assurance Manager (QAM), Project Managers, and the technical staff are appropriately informed to permit adequate execution of their QA responsibilities. The QAM must be available to provide review of work plans, scopes of work, task orders, RFPs, and QA Project Plans. In addition, the QAM will (1) organize and schedule appropriate training sessions for S-CUBED staff, (2) provide example QA Project Plans for various generalized situations, and (3) provide criteria to assist Division personnel in determining the level of quality control needed for different projects.

This QA Program Plan provides for technical audits to assure that all aspects of the laboratory's Quality Assurance Program are operational and that related policies are being observed. The QAM is authorized to conduct a combination of system and performance audits of selected projects with regard to Quality Assurance/Quality Control activities. These audits can include examining selected scopes of work, quality assurance plans, and project progress reports, submitting blind analytical reference samples for analysis, on-site review of the performance and procedures of sampling and analysis teams, etc. Reports of auditing efforts will be prepared and submitted to cognizant parties, and shall include recommended remedial actions, if appropriate.

S-CUBED shall meet the following Quality Assurance Program requirements:

- (1) The QA Program shall be executed by qualified personnel trained in QA theory and practice. The QAM will be organizationally independent, as described in Section 2.0.
- (2) Facilities, equipment, and services, which directly or indirectly impact data quality or integrity, shall be routinely inspected and maintained.
- (3) All data generated by or for S-CUBED must meet the following requirements:
  - (a) Analytical methods and procedures used in measurement and monitoring efforts will be fully documented and shall include quality control procedures.
  - (b) Quality Assurance Project Plans, standard operating procedures, or protocols approved by S-CUBED shall be developed prior to and implemented in all measurement and monitoring activities.

- (c) Acceptance criteria for data quality shall be determined before the data collection effort begins.
- (d) Where appropriate, all reported data shall include statements of precision, accuracy, representativeness, completeness, comparability, and limits of detection.
- (4) Data processing procedures shall be documented, reviewed, and revised as required to meet S-CUBED's data quality requirements. Data shall be validated according to specified criteria.
- (5) The QAM, working with the Project Managers, shall develop and implement a mechanism for timely corrective action. The QAM shall provide regular reports regarding QA progress, associated or potential problems, and data quality assessments to S-CUBED management.
- (6) This QA Program Plan shall be reviewed at least annually by the QAM, and others as deemed necessary, and updated as required.
- (7) Resources allocated for the QA Program shall be appropriate for implementing this policy.

S-CUBED is committed to the implementation of this Quality Assurance Program to ensure that all aspects of data quality are adequate to meet internal specifications and clients' needs.

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## 2.0 *QUALITY ASSURANCE MANAGEMENT*

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The S-CUBED Quality Assurance Program has been in force as a result of our comprehensive quality assurance attitude since the founding of the Division (formerly Company). This program covers all activities, including the purchase of materials and the manufacture of commercial products, and specifically addresses sampling and analysis activities for environmental assessment. This ongoing Quality Assurance Program provides guidance for all S-CUBED projects as necessary to meet project objectives.

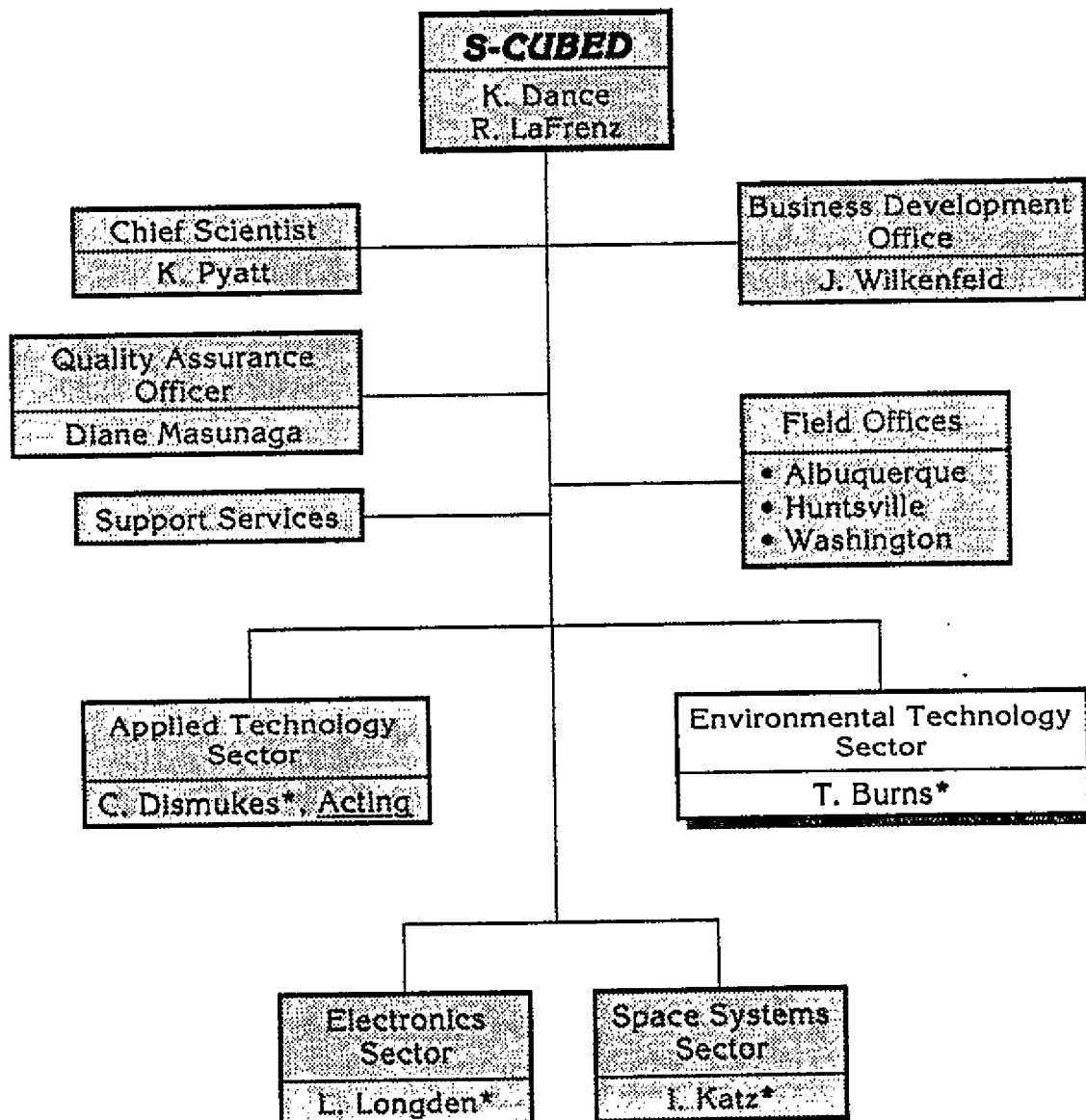
### 2.1 ASSIGNMENT OF RESPONSIBILITIES

An individual is assigned as Quality Assurance Manager (QAM) for the Environmental Technology Sector (ETS). The QAM reports directly to the Senior Vice President and Manager of the Environmental Technology Sector. The QAM interacts with Project and Program Managers to provide assistance, direction, and review on an as-needed basis. He also keeps the S-CUBED Division Quality Assurance Officer apprised of quality program status.

#### 2.1.1 The Quality Assurance Manager

The QAM serves as the ETG Quality Assurance Program information focal point. The QAM is responsible for providing advice and assistance to laboratory staff members in the quality assurance and quality control aspects of both sampling and analysis. This individual also ensures through an auditing function that laboratory activities are in compliance with appropriate policies and procedures. The development, evaluation, and documentation of QA policy and procedures appropriate to S-CUBED data generating activities are coordinated and monitored by the QAM. Evaluation of QA Program Plan cost-effectiveness, and recommendations for improvement of the plan, also are the responsibility of the QAM. The QAM should be aware of all contractual QA requirements. In order to facilitate this, he will be provided with Contract Briefs for all new contracts, copies of all Sample Delivery Notice forms, and Work Orders for all new Contract Laboratory Program (CLP) work, particularly pertaining to special analytical services (SAS).

The S-CUBED QAM is responsible for all QA program activities within the ETG. In order to carry out these responsibilities effectively, the Quality Assurance Manager must be organizationally independent of all programs involved in data generation. The Division Organization is shown in Figure 2.1, and the ETG Organization is shown in Figure 2.2.



\*Division Senior Vice President

Figure 2.1. Organizational Status of the S-CUBED Division

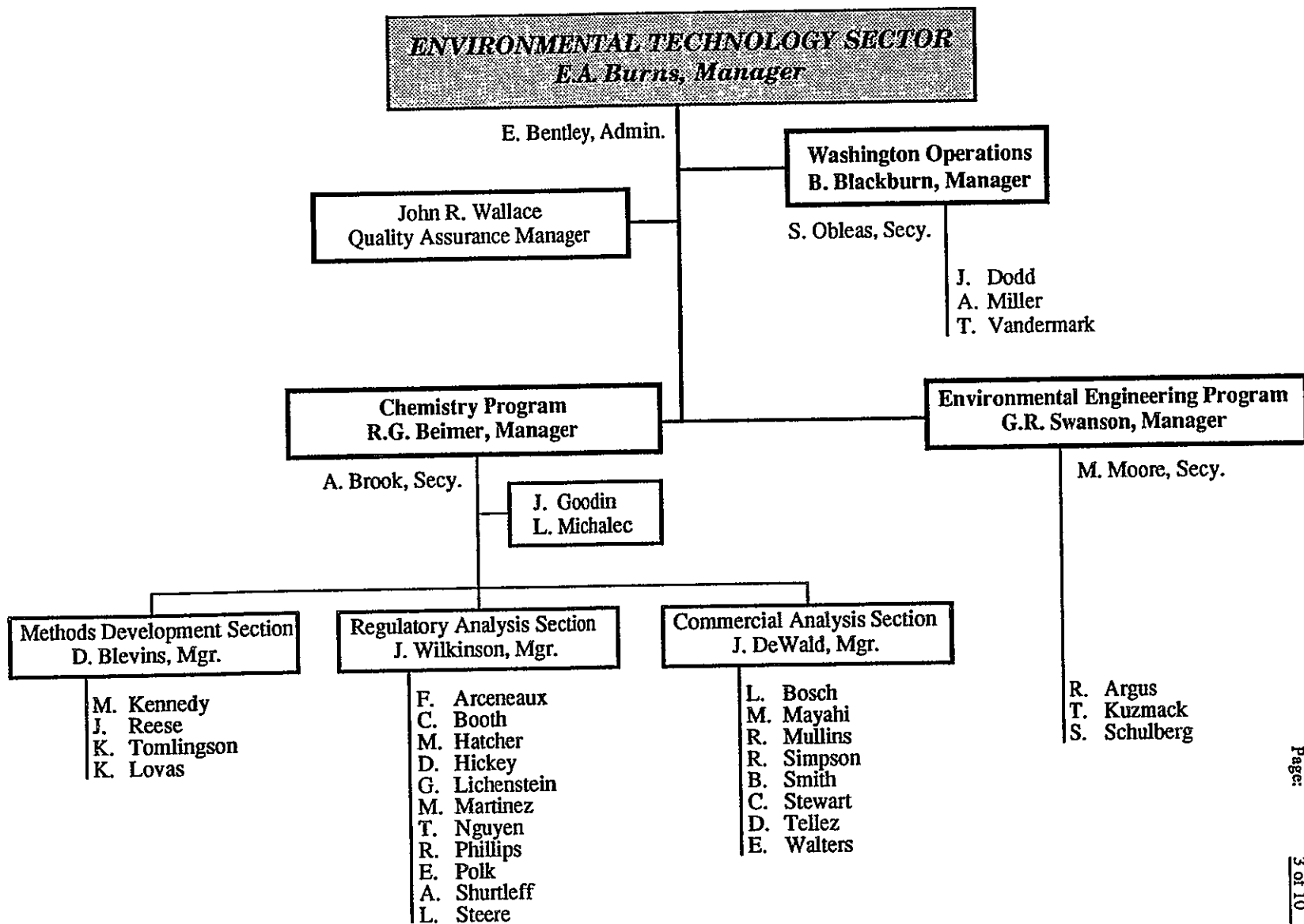


Figure 2.2. S-CUBED Environmental Technology Sector Organization

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The Quality Assurance Manager provides input and interfaces with the Project Managers to ensure that specific quality control plans are prepared prior to commencement of sampling and analysis activities. This individual is available to review the QA criteria for each project and ensures that adequate quality assurance indoctrination and quality assurance documentation have been provided. The QAM is responsible for ensuring that the following activities are performed:

- QA indoctrination of personnel, as needed
- Procedure review and approval
- Sample identification and traceability
- Quality control
- Data assessment
- QA audits
- Feedback and corrective action.

The QAM acts as an advisor to the Environmental Technology Group Vice President and periodically reports on the progress and deficiencies of the Group's QA program, identifying specific needs and recommending corrective action as appropriate.

In a consultant capacity, the QAM makes recommendations to the professional staff (Project Managers, Task Managers, Scientific Staff, etc.) for appropriate and necessary QA methods and plans to ensure the quality of the research data produced.

Smooth internal functioning of the S-CUBED Environmental Technology Sector is dependent on effective communication between all personnel associated with laboratory measurement project activities. This is most effectively accomplished by providing a clear understanding of individual responsibilities and the way such responsibilities relate to one another. In this context, the QAM is responsible for motivating personnel such that an appreciation is developed for the importance of their respective roles to the overall success of the program.

The S-CUBED QAM will also conduct technical audits to determine the quality of operation of various functions and activities. The objective of such audits is to assess and document (1) facilities; (2) equipment; (3) QC systems; (4) record keeping; (5) data validation; (6) operation, maintenance, and calibration procedures; and (7) reporting aspects of the total quality control program for a project. The review should accomplish the following:

- (a) Identification of existing system documentation; i.e., maintenance manuals, organizational structure, operating procedures, etc;

- (b) Evaluation of the adequacy of the procedures as documented; and
- (c) Evaluation of the degree of use and adherence to the documented procedures in day-to-day operations, based on observed conditions and a review of applicable records on file.

### 2.1.2 Project Managers

All S-CUBED measurement activities are under the purview of a Project Manager (PM). It is the responsibility of each Project Manager to satisfy all technical and administrative aspects pertinent to these measurement activities. In order to fulfill this responsibility, the PM must be:

- (1) Knowledgeable in the specific field of endeavor required for the performance of work, and
- (2) Sufficiently knowledgeable in the quality assurance requirements of the work to assure and document the quality of all resulting information adequately, such as research data and conclusions.

To ensure the quality of the task product, the PM must act in a collaborative role with the S-CUBED QAM to determine which specific QA techniques are most appropriate to a particular activity for conformance to Company policy. In many situations, the PM may delegate this responsibility to a specific Task Manager. The PM or Task Manager is responsible for the preparation of a QA Project Plan when required, and assumes responsibility for QA Project Plan implementation.

In order to assure that information resulting from work performance is of acceptable quality, all quality assurance aspects of work performance must be defined prior to the initiation of any activity. Planning involves anticipation of events that relate to or impact data quality, including contingency planning for unforeseeable failures/problems and objective independent evaluation of quality as the task progresses. Normally, planning takes the form of a QA Project Plan that will be prepared by the appropriate Project or Task Manager. Planning covers all aspects of data acquisition, including:

- Development of procedure checklists to be followed in each aspect of sampling and analysis or other measurement efforts.
- Delegation of responsibility for the implementation of specific QA procedures.
- Designation of communication lines between management and data-generating staff for reporting concerns about weaknesses (or excesses) in QC procedures.
- Delegation of responsibility for in-house review of data and calculations.

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- Formalization of procedures for continued review and improvement of the QA program.

A second QA method employed by the Project Manager is to make periodic on-site inspections and quality assurance audits. These activities are performed to verify that the QC procedures listed on checklists are being performed and that they are sufficient. These inspections are typically performed for sampling, analysis and data management activities.

### 2.1.3 QA Requirements for Subcontracts

In the event that S-CUBED subcontracts a specific work assignment or data generating activity to a secondary individual or organization, S-CUBED will monitor the information it receives to ensure it meets the same quality requirements as those established for internal S-CUBED programs. These requirements will follow the guidelines established in S-CUBED's QA Program Plan. For major task activities involving sampling, analysis, or analytical methods development, S-CUBED will specify that a QA Project Plan be prepared by the subcontractor addressing the criteria outlined in Section 5.1. This plan will be reviewed by S-CUBED's QA Manager to ensure that it meets S-CUBED's and/or contract requirements.

For smaller projects or routine measurement activities, S-CUBED will plan and establish QA requirements consistent with project and program needs. Specific instructions will be provided to the subcontractor regarding data quality generation, quality control, data processing, data quality assessment, and corrective action requirements. It will be the responsibility of the S-CUBED Project Manager to monitor data received under a subcontract for adequate quality.

Surveillance activities include frequent communication with the subcontractor. Typically, weekly teleconferences are held between the S-CUBED Project Manager, the subcontractor's Task Manager, and the QAM (as required). The discussions address current project status, QA/QC activities and results, difficulties (i.e., outlier data), and corrective action. In addition, a written monthly progress report is required. Reports shall address the above topics in detail. Teleconference documentation and progress reports shall be archived in the project file.

## 2.2 DOCUMENTATION

The Program Manager or his designee is responsible for project task documentation. To ensure the quality of documentation, the Project Manager shall act in collaboration with the S-CUBED QAM to determine specific QA techniques for application to a particular documentation task. In most cases, this will consist of an independent document review by a member of the project team not associated with document preparation.

Documentation task areas include the preparation and/or revision of (1) standard procedures and project plans (e.g., internal standard operating procedures, sampling and analysis plans, test plans, quality assurance project plans), (2) reports (e.g., progress reports, environmental assessments, analytical data reports, final project reports), (3) method protocols, (4) instructional support materials (e.g., method instruction manuals, audiovisual aids, publicity brochures, public presentations), and (5) regulatory/ technical background documents. Documentation task areas are discussed in the following subsections.

#### 2.2.1 Standard Procedures and Project Plans

Prior to the initiation of any specific measurement task, procedures and a plan for implementation must be written, reviewed, and approved by the Project Manager or his designee. All information will be documented and maintained in a central location. Any procedure used in the collection of final data will be properly documented and referenced. Documented information shall include:

- Material and Equipment Procurements
- Cleanliness
- Sampling Procedures
- Metrology and Standardization
- Calibration Procedures
- Analytical Procedures
- Data Collection and Reporting Procedures
- Health and Safety Procedures
- Auditing Procedures

#### 2.2.2 Reports

Project results during a particular reporting period must be documented by the assigned task leader and reviewed and approved by the Project Manager. All reports approved for release will be maintained in a central location. All information relevant to the preparation of project reports will be appropriately indexed and referenced. Relevant information includes:

- Sampling Notes and Raw Data,
- Sample Custody Documentation,
- Sample Preparation and Analytical Raw Data,
- Analytical Results Summaries, and

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- QA/QC Results Summaries.

### 2.2.3 Protocols

For tasks involving the development and evaluation of new methodologies, the modification of existing methodologies, or the revision of written procedures and documentation for existing methodologies, detailed protocols must be written by the assigned task leader and reviewed by the Project Manager. When required, revisions shall be made by a documentation specialist in collaboration with the task leader. Each written protocol for internal use must be reviewed and approved by the QAM to ensure that the appropriate quality control measures are properly defined and implemented. All documentation related to protocol development will be maintained in a central file. Specific task areas for protocol documentation are as follows:

- Sampling methodologies for air, water, soil and biological environmental matrices and for municipal and industrial waste streams,
- Physical and chemical waste characterization test methodologies for the various sample matrices,
- Sample preparation and analytical methodologies for the various sample matrices, and
- Quality assurance, control, and audit methodologies.

### 2.2.4 Instructional Materials

Instructional materials are developed (1) to help standardize the proper implementation and performance of standard physical, chemical, and biological test methods across all laboratories using such methods, and (2) to increase the factual understanding of, and involvement with, relevant environmental problems and policies in the public awareness. Tasks which involve the preparation of instructional materials require the review and approval of the Project Manager. All documentation related to the development of instructional materials are maintained in a central location. Specific instructional materials task areas include the organization, preparation, and dissemination of the following:

- Training manuals,
- Audiovisual aids,
- Videotape demonstrations,
- Publicity brochures, fact sheets, and pamphlets,
- Written and oral presentations, and

- Workshops, symposia, conferences.

#### 2.2.5 Regulatory/Technical Background Documents

Tasks which involve the preparation, review, and/or revision of technically sound, defensible background documents capable of supporting regulatory rulemaking or regulatory changes require (1) detailed literature review, (2) expert consultation, (3) detailed data evaluations and data quality assessments, (4) coordination with several local, state, and/or federal agency offices, (5) document preparation and editing by technically qualified writers, and (6) overall integration to ensure that the information upon which the background document is based satisfies the applicable regulatory needs. Quality assurance of these documentation activities will include the interactive reviews and approvals of the Project Manager and the QAM. Careful records of every source of information and data related to the preparation of background documents will be maintained in secure, centrally located files. Confidential material will be kept in a locked cabinet in the care of the Project Manager or the Document Control Officer.

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### 3.0 PERSONNEL QUALIFICATIONS

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The Project Manager shall ensure that all personnel performing tasks and functions related to data quality have the needed education, training and experience to perform their respective tasks. This includes laboratory technicians, analysts, maintenance technicians, supervisors, and statisticians. The Company encourages, where appropriate, participation in seminars, short courses and professional meetings designed to increase the level of quality assurance understanding within and between Company personnel.

#### 3.1. QUALITY ASSURANCE MANAGER

The S-CUBED Quality Assurance Manager (QAM) must have sufficient professional and administrative expertise to meet the following criteria:

- Comprehensive professional and administrative experience on a level sufficient to interface effectively with Project Managers and other professional staff members and technical personnel.
- Continual participation in QA professional activities on a level sufficient to maintain cognizance in current and ongoing developments within the quality assurance field.
- A statistical background is highly desirable and the knowledge and experience in a scientific discipline is necessary.
- Knowledge of appropriate federal laws, agency regulations and guidelines with respect to environmental operations and related systems.
- Knowledge of current user requirements in the Quality Assurance area.

Dr. J.R. Wallace serves as QAM at S-CUBED. Dr. Wallace, who earned his Ph.D. in Chemistry at the University of Illinois in 1974, has extensive experience in quality assurance. He currently is the manager of a contract to provide QA support to the USEPA Risk Reduction Engineering Laboratory in Cincinnati, for which his responsibilities include the development of QA/QC procedures, critical review of QA Project Plans, and the review of project final reports. Dr. Wallace is experienced in all major areas of chemical analysis, including chromatography and mass spectroscopy. He has developed methods and instruments for chemical analysis and is experienced in project and laboratory management.

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Dr. Wallace is also assisted on an as-needed basis by the following S-CUBED professionals dedicated to the QA programs:

- Mr. W.B. Blackburn - As the Manager, Environmental Technology Sector, Washington DC Operation, Mr. Blackburn is responsible for coordinating Chemistry Program and Environmental Engineering Program support to EPA and DoD sponsors. He is experienced in all phases of QA/QC management and implementation. He has considerable experience in the technical review of RREL Quality Assurance Project Plans and Final Reports, and implementation of Technical Systems Audits of RREL contractors.
- Ms. J.E. Goodin - Ms. Goodin provides Quality Assurance Project Plan reviews for the RREL Quality Assurance Technical Service project. She routinely supports internal QA.

### 3.2 PROJECT MANAGERS

The role of all S-CUBED Project Managers is similar in nature to that of the QAM in the sense that they must possess expertise in both their technical field and QA. Where Project Managers are concerned, however, the emphasis in these two areas is the converse of that of the QAM. Project Managers are primarily responsible for a high level of technical expertise in their respective scientific field, but expertise in Quality Assurance must exist on a level sufficient to assure and document the quality of their respective efforts adequately. In this way, the Project Manager function complements the QAM function in that the strengths and weaknesses of both personnel categories are mutually complemented and balanced. The result is that research data and conclusions derived from individual project activities are of a quality consistent with S-CUBED QA policy. To attain this goal, Project Managers must have the capability to work cooperatively with S-CUBED's QA organization to structure individual project activities and goals in a manner consistent with QA needs. It is the Project Manager's responsibility to integrate an optimum level of quality assurance directives to guarantee suitable research data and conclusions of a reliable quality. Such functions include the formative development of a Quality Assurance Project Plan for individual project activities as well as cooperation with auditing efforts as deemed appropriate by the QAM.

### 3.3 RESEARCH AND SUPPORT PERSONNEL

The Project Manager shall review personnel qualifications to ensure that individuals assigned to a project possess sufficient quality experience and expertise to conduct assigned tasks effectively.

In those cases where research and support personnel are required to participate in projects involving field sampling and laboratory analysis efforts, certification programs may be deemed necessary by the

Maxwell, S-CUBED Division

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PM. Certification may include external audit programs for performance evaluation and/or accredited training courses in the respective areas of specialization. If work-related deficiencies are observed, the Project Manager will initiate any corrective actions necessary to raise performance quality to acceptable levels.

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#### 4.0 FACILITIES, EQUIPMENT, AND CONSUMABLES

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This section describes the QA requirements for the selection, evaluation, and maintenance of S-CUBED equipment, facilities, and consumables. Prior to the initiation of any project activity, the requirements for these items will be identified based on the nature of the project. The equipment, facilities, and consumables which are identified specifically for analytical work will be evaluated appropriately.

##### 4.1 FACILITIES AND EQUIPMENT

The laboratories and other operational areas shall be neat and orderly. Laboratory benches shall be kept clear of all but the necessary tools and glassware. Personal items shall not be kept in the working area.

When new instruments are purchased, they shall be checked after initial setup using reference and calibration materials to establish whether detection limits, ease of operation, and automated procedures meet the anticipated performance standards and whether these standards are adequate to provide the desired data quality. Analytical instrumentation associated with the production of data must also meet requirements for precision and accuracy. These parameters, along with the instrument detection limit, will be evaluated through the analysis of control samples of known concentration.

Good laboratory maintenance requires complete manuals, kept in a convenient place so that they are readily available to the appropriate personnel. Each Section Manager (Figure 2.2) is responsible for assuring the availability of manuals, and for maintaining a reference copy as appropriate.

Equipment must conform to specifications resulting in good data quality. Criteria for this assessment include the basic environmental aspects of the facility, such as lighting, humidity, temperature, and housekeeping services. Where field sampling equipment is under consideration, quality assurance audits and subsequent verification of equipment adequacy shall be performed. Where standard field assessment techniques, such as those required by EPA, are being utilized, the Project Manager will verify that equipment being used meets established EPA specifications and is in such condition that the production of quality data is guaranteed. Careful attention must be paid to the maintenance of sample integrity through examination of the sampling location area, the optimal functioning of all the sampling equipment, and the functioning of supportive sampling equipment such as balances and reagents.

Inspection and preventive maintenance activities shall be conducted on a periodic basis to ensure the proper functioning of all facilities and equipment used for the generation of data. Inspection and maintenance activities shall be performed by qualified personnel who must use accepted documented procedures. All inspection and preventive maintenance activities must be thoroughly documented such

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that records clearly specify actions performed, such as adjustments made or calibration actions taken. Records shall be readily accessible to personnel.

#### 4.2 CONSUMABLES

For the purpose of this document, the term "consumable" means all materials that are used during an S-CUBED project activity that are either consumed as a result of that activity or are rendered useless for further activity. These consumables shall be of a quality sufficient to preclude contamination or interference with the resulting conclusions and data. In most cases, this requirement is specified by the customer or in analytical protocols.

Care must be exercised in the purchase of chemical reagents. Reagent-grade chemicals often contain significant levels (ppm) of trace metals and other impurities. In certain cases, specially purified reagents may be required. Once delivered, reagents should be checked for purity by preparing control or blank samples and analyzing them in the normal manner. This quality control procedure shall be accomplished prior to any actual analyses. Such preliminary checking of reagent quality will allow time for reagent replacement or purification.

Solvents used are to be of pesticide grade or equivalent quality. Use of high quality reagents is important to minimize the probability of acquiring unsatisfactory lots of material, which would require repurification or replacement.

The laboratory reagent water source is continually assessed through the analysis of method blanks for both the organic and inorganic compound determinations. Similarly, all reagents (i.e., acids, indicators, derivatization reagents) are assessed for purity through the analysis of method or reagent blanks. Sodium sulfate, silica gel, alumina, and Florisil used in liquid-solid chromatographic separations may require cleanup by extraction with organic solvent prior to use. All solvents, reagents, and supplies must be dated as they are received.

Preparation dates shall be noted on standards and records shall be maintained of the vendor and lot number for all standards. Any outdated standards are disposed of.

For field sampling or monitoring efforts, consumables refer to items such as impinger reagents or filter systems or other kinds of consumable materials. Such materials shall be of a quality sufficient to preclude contamination of the samples being acquired. Frequently, the standard sampling methods specify the degree of purity and the nature of reagents in materials.

## 5.0 DATA GENERATION

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Environmentally related measurement activities constitute the primary area of data generation. To assure data integrity, foreseeable contingencies are carefully planned for during the formulation of individual project plans. In this section, project plans and their importance to the overall quality assurance effort will be expanded upon. All data generated must be scientifically valid, defensible, comparable, and of known precision and accuracy.

### 5.1 QUALITY ASSURANCE PROJECT PLANS

Projects undertaken by S-CUBED will have associated project plans whenever required by contract. A plan relates the overall project objectives, including specific measurements that are to be made, with emphasis on the quality assurance aspects. QA Project Plans will include the following sections:

- (1) Title page with provisions for approval signature,
- (2) Table of contents,
- (3) Project description,
- (4) Project organization and responsibilities,
- (5) Quality assurance objectives for measurement data in terms of precision, accuracy, completeness, representativeness, and comparability,
- (6) Sampling procedures,
- (7) Sample custody,
- (8) Calibration procedures,
- (9) Analytical procedures,
- (10) Data reduction, validation, and reporting
- (11) Internal quality control checks
- (12) Plans for performance and systems audits, including frequency,
- (13) Preventive maintenance procedures and schedule,

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- (14) Specific routine procedures used to assess data, precision, accuracy, completeness, representativeness, and comparability of the specific measurement parameters involved,
- (15) Corrective action, and
- (16) Quality assurance reports to management.

The S-CUBED QAM will review all QA Project Plans for their applicability to the proposed project. All such QA plans will be maintained in a current file which is readily accessible.

## 5.2 STANDARD OPERATING PROCEDURES

A Standard Operating Procedure (SOP) is a detailed, step-by-step set of instructions on how to perform a specific activity. For example, the procedure for continuous liquid/liquid extraction can be written in the form of an SOP. Activities which are adaptable to SOP protocols include the following:

- (1) General sampling and network design,
- (2) Specific sampling site selection,
- (3) Sampling and analytical methodology,
- (4) Probe collection devices, storage containers and sample additives or preservatives,
- (5) Methods of cleaning sample containers,
- (6) Special precautions such as heat, light, reactivity, combustibility, and holding times,
- (7) Federal references or alternative equivalent test procedures,
- (8) Calibration and standardization,
- (9) Preventive and remedial maintenance,
- (10) Extraction or concentration procedures,
- (11) Documentation and document control,
- (12) Sample custody,
- (13) Transportation,
- (14) Safety,

(15) Data handling and reduction procedures, and

(16) Service contracts.

All standard operating procedures developed by S-CUBED will be sufficiently complete and detailed to ensure that data of known quality are generated to meet measurement objectives and that there is a minimum loss of data from out-of-control conditions. In addition, all standard operating procedures will be:

- Adequate enough to establish traceability of standards, instrumentation, samples, and environmental data.
- Simple, so a user with basic education, experience and/or training can properly use them.
- Complete enough so the user/reader follows the directions in a stepwise manner through the sampling, analysis, and data handling.
- Consistent with sound scientific/engineering principles.
- Consistent with current regulations and guidelines, such as those promulgated by the EPA.
- Consistent with the instrument manufacturer's specific instruction manuals.

Documentation for all standard operating procedures will be sufficiently complete to:

- Record the performance of all tasks and their results.
- Explain the cause of missing data.
- Demonstrate the validation of data each time they are recorded, calculated or transcribed.

SOPs shall be written according to the specific instructions provided in Appendix A, *Writing Standard Operating Procedures* (SOP No. 20-001-00).

All formalized S-CUBED Standard Operating Procedures which are incorporated into any measurement activity shall be cited specifically by reference. Any such citation will constitute a stipulation by the Project Manager that all mandates of the SOP will be followed exactly, without

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deviation. Under those special circumstances where the nature of the project involved requires deviation from the SOP, the deviation will be endorsed by the Project Manager.

### 5.3 QUALITY ASSURANCE IN SAMPLING

Sampling activity shall be carried out so as to provide laboratory personnel with sufficient material for analysis which is representative of the sample source without compromising sample integrity. The remainder of this section deals with the general aspects of good sampling practices, sampling quality control, and how these aspects are monitored by the quality assurance program. Specific or alternative quality assurance measures for sampling are described in the project-specific QA Project Plans.

#### 5.3.1 Written Protocols

Sampling methods used on any project must be available to the sampling personnel in written form, preferably in the format indicated in Appendix A.

#### 5.3.2 Good Sampling Practices

There are two steps in obtaining representative samples. The first step is to follow a cleanliness control protocol. These protocols are found in the laboratory SOPs or in the QA Project Plans. Gases must be acquired in calibrated sampling devices which have been evacuated prior to sample acquisition or purged with several volumes of the gaseous sample. Homogeneity of the area from which the sample is taken is a concern; every effort will be made to sample from a point where mixing is maximized. Because liquids in process and waste streams may not mix well, efforts will be made to sample where the liquid is most homogeneous or to take samples from several points and combine them. Solids tend to be more heterogeneous than liquids; if a bulk solid shows major heterogeneity, a composite sample is necessary. Once representative samples have been acquired, steps to preserve certain samples may be required. In addition, some samples may require special shipping considerations in order to reduce the likelihood of decomposition. The on-site sampling supervisor is responsible for seeing that all aspects of sampling, sample preservation, packaging, and shipping are carried out in the prescribed manner.

#### 5.3.3 Quality Control in Sampling

Another step in establishing and maintaining a high level of sample reliability is to follow the quality control program designated in the QA Project Plan. This plan must provide for:

- Reference to or incorporation of accepted sampling techniques in the sampling plan;

- Procedures for documenting and justifying any field actions contrary to the QAPP;
- Documentation of all pre-field activities such as equipment check-out, calibrations, and container storage and preparation;
- Documentation of field measurement quality control data;
- Documentation of field activities;
- Documentation of post-field activities including sample shipment and receipt, field team debriefing and equipment check-in;
- Generation of quality control samples including duplicate samples, field blanks, equipment blanks, and trip blanks; and
- The use of these samples in the context of data evaluation, with details of the methods employed (including statistical methods) and of the criteria upon which the information generated will be judged.

Sample labels will be provided for each sample, which include the following items at a minimum:

- Sample identification code number;
- Description of sample source (i.e., plant and location);
- Date and time of acquisition;
- Volume or weight of sample;
- Sample description (i.e., type of media and preservative);
- Person who collected sample; and
- Other comments.

Samples are summarized in a Field Tracking form which includes, as a minimum, a list of all samples collected along with a brief description, the date and time of collection, and the sampler.

The QA Project Plan will designate an individual as the sample custodian, who will be responsible for maintaining sample custody until it is relinquished to the laboratory. Sample custody means that samples are under the view and control of an individual, or in a secure, locked area. For those samples requiring custody, a record will be maintained demonstrating continuous custody from sample collection to final disposal.

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One copy of the sheet will be securely attached to or packaged with the sample and the other maintained by the sampling supervisor.

If required for the specific project, blanks, duplicate samples, and the shipping and storage of reference materials will be used. Each sampling procedure to be used will be accompanied by a checklist to be filled out at the time of acquisition.

#### 5.4 QUALITY ASSURANCE IN ANALYSIS

Quality assurance in analysis is accomplished by:

- Establishing good laboratory practices,
- Maintaining a quality control program, and
- Monitoring the accuracy, precision and detection limits with which results are produced.

Aspects of the first two of these three activities are discussed below. Discussion of the third activity is presented in Section 7.0 of this document.

##### 5.4.1 Good Laboratory Practices

In general terms, good laboratory practice requires:

- Facilities and equipment which are adequate for required analyses.
- Methods which are current and which meet minimum criteria for accuracy, precision, detectability, and reliability.
- Personnel who are educated and experienced with the necessary equipment and methods.
- Sample and reagent storage suitable for avoiding sample degradation or contamination.
- Record keeping which permits all aspects of an analysis to be reconstructed after the fact.
- Incorporation of specific QC procedures and samples (e.g., spikes, replicates, etc.) into every analytical procedure. Specific QC criteria must be satisfied before analytical results can be reported.

- An independent QA Manager who performs the functions described elsewhere in this Plan.

In addition to these general guidelines, the term *Good Laboratory Practice* also connotes specific regulations promulgated by various federal agencies and published in the Code of Federal Regulations (e.g., 21 CFR 58, 40 CFR 160, 40 CFR 792). S-CUBED does follow the general intent but not necessarily all the details of such regulations, and in the event that a client requires *Good Laboratory Practice*, the Project Manager must determine before contract initiation exactly what this entails.

In terms of compliance with government requirements, *Good Laboratory Practice* at S-CUBED is dominated by the requirements of the EPA Contract Laboratory Program. This program specifies requirements for equipment, facilities, methods, record keeping, sample storage, and quality control, and thus has much the same effect as the above-cited *Good Laboratory Practice* regulations.

#### 5.4.2 Quality Control in Analysis

There are several aspects of analytical quality control which are carried out on a routine basis in order to have consistent and useful results. These include, but are not necessarily limited to, the following:

- Calibrations and instrument condition checks,
- Laboratory check standard,
- Blanks of various types,
- Surrogates,
- Internal standards,
- Spiked blanks,
- Matrix spikes, and
- Replicates.

(Definitions of these terms are found in Section 7.1 of this report.)

These analyses are performed to establish the precision and accuracy of the laboratory effort and to verify that analytical functions are in control.

The frequency and nature of all such QC samples will be specified in writing before analyses can begin. Typically, the first six types of QC samples are specified internally by the method SOP or other

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document, and are performed uniformly for all clients. The frequency of matrix spikes and matrix spike duplicates will vary with the client, but must be designated before analysis begins. In any case, contractual requirements pertaining to the frequency and types of QC samples will take priority, although minimum QC levels are nevertheless specified internally.

Method validation is required whenever a procedure new to laboratory personnel is to be performed or whenever a routine laboratory procedure is applied to a new type of sample matrix. The primary concern in method validation is the precision and accuracy associated with field samples as opposed to laboratory standards. A major portion of this effort is related to evaluating potential sample matrix effects through the analysis of spikes and replicates.

## 6.0 DATA MANAGEMENT

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### 6.1 LABORATORY ANALYSES

The function of quality assurance in data management is to evaluate and monitor the reliability of information generated for particular samples and to ensure that information is documented and reported accurately and reliably. The intent is to eliminate confusion or problems resulting from missing, incomplete or poorly documented data. Efforts in this area are primarily concerned with delegation of responsibility for data tracking, documentation, calculations and reporting. It is essential that any analytical result can be substantiated at a later date by reconstructing all calculations and records, should such be needed.

Permanent records are maintained by the Document Control Officer (DCO). Requests for access to these records are made to the DCO, who regulates requests for any confidential or proprietary data. The DCO also tracks records which have been removed for project-related work. As an additional responsibility, the DCO ensures that all records are locatable and archived according to contract. All records are kept for 180 days beyond release of the report, unless the contract or QA Project Plan specifies otherwise. These documents are kept until the Project Manager instructs the DCO to dispose of them. All archived material will have a cover sheet containing the date entered and the disposal date. Standard Operating Procedures are being developed regarding the documentation methods.

### 6.2 SAMPLE AND DATA TRACKING

Sample and data tracking begin prior to the sampling effort when the desired sample types, locations and the ultimate uses of the data are identified. At this point, all sampling and data handling procedures can be specified. In most cases, these procedures should be covered by one or more of S-CUBED's Standard Operating Procedures (SOPs) dealing with, for example, chain of custody or shipping.

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## 7.0 MEASUREMENT OF DATA QUALITY

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The assessment of data quality is the end result of a comprehensive QC/QA program and is comprised of five basic components:

- (1) Accuracy.
- (2) Precision.
- (3) Completeness.
- (4) Representativeness.
- (5) Comparability.

Frequently, the assessment of a sixth component is also required to ensure that low level or undetected results are of known significance, or to define the limits of applicability of a measurement system or method:

- (6) Limits of Detection.

### 7.1 DEFINITIONS

#### 7.1.1 Acceptance Criteria

Acceptance criteria - QC goals which must be achieved before data are reported.

#### 7.1.2 Accuracy

The accuracy of a given measurement is the degree to which the determined value compares to the true value. Examples of approaches for determining accuracy include:

- Recovery of matrix spikes and surrogates.
- Analysis of Standard Reference materials, such as those provided by the National Bureau of Standards, when such materials closely approximate the samples of interest.
- Analysis by multiple methods, or employment of a referee method.
- Analysis of artificial samples which are very similar to the samples of interest, but which contain known amounts of analyte.

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Each project plan will set forth specific methods to be used in determining the accuracy of the acquired data.

#### 7.1.3 Blank

A blank is an aliquot of analyte-free material which is taken through the entire process for the purpose of monitoring the occurrence of contamination.

A *method blank* is an analyte-free solid or water sample which is carried through the entire extraction-cleanup-analysis procedure. A *reagent blank* includes only reagents that are employed in the analysis. A *field blank* is taken to the field in a sealed container and transported back to the laboratory with the sample containers. *Trip blanks* remain unopened in the field; *equipment blanks* are opened and their contents taken through the sample collection procedure as a check on sampling device cleanliness.

#### 7.1.4 Comparability

Comparability is a measure of the confidence with which one data set can be compared with another. Comparability is achieved by employing standardized analytical methods, reporting units, and data forms.

#### 7.1.5 Completeness

Completeness is calculated as the amount of valid data acquired compared to the amount of data planned to be acquired to achieve a particular statistical level of confidence in the data.

#### 7.1.6 Continuing Calibration Standard

A continuing calibration standard is a standard that is used on a frequent basis to check the calibration of the instrumentation.

#### 7.1.7 Limits of Detection

Limits of detection are defined relative to the background noise level generated by a measurement system. The most frequently defined limits of detection are the Method Detection Limits (MDL). Formulas for calculating the MDL are specific to the type of measurement system and are presented in the project specific QA Project Plan.

#### 7.1.8 Matrix Spike (MS)

Predetermined quantities of stock solution of certain analytes are added to a sample matrix prior to processing. Percent recoveries are calculated for each of the analytes detected.

#### 7.1.9 Matrix Spike Duplicate (MSD)

Samples are split into duplicates, spiked, and analyzed. The relative percent difference between the duplicate samples is calculated and used to assess analytical precision.

#### 7.1.10 Precision

The precision is the measurement of agreement of a set of replicate results among themselves without assumption of any prior information as to the true result. It is assessed by replicate sample analysis.

#### 7.1.11 Independent Check Standard (ICS)

An IC standard is an independently prepared standard from a source other than that used to calibrate the instrument. The ICS provides an independent verification of the working standard.

#### 7.1.12 Representativeness

The term representativeness refers to the degree with which a small number of data are representative of the total possible data set from which they are drawn. The acquisition of a representative sample is usually based on a statistical approach which attempts to allow for natural variability.

#### 7.1.13 Replicate/Duplicate

Replicate samples are prepared by dividing a sample into separate aliquots. Duplicate samples are prepared by dividing the sample in two.

*Sample Replicates* are multiple samples collected at the same time from the same source in order to measure sampling variability. *Method Replicates* are sub-divided in the laboratory to check the reproducibility of the analytical method. *Replicate Standards* are standards run in multiples to test the reproducibility of standardization process.

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#### 7.1.14 Spiked Blanks

Spiked blanks are pure solutions or solids containing known amounts of analytes. Spiked blanks undergo the entire analytical process (extraction, cleanup, and analysis). They are often included routinely in every batch of samples as an indication that the analysis was performed correctly. In contrast, matrix spikes may exhibit poor recovery simply due to a difficult matrix.

#### 7.1.15 Standard Reference Material (SRM) and Internal Reference Material (IRM)

An SRM is complex but thoroughly characterized material containing known amounts of analyte. SRMS are typically obtained from the NBS or, less frequently, the EPA or ASTM. An IRM is similar to an SRM but has only been characterized internally. IRMs are typically included in each batch of samples to assure long-term reproducibility.

#### 7.1.16 Standards

Standards are solutions made up to known concentrations in order to check the operation of the instrument or to make up a standard curve.

#### 7.1.17 Standard Curve

A standard curve is a curve which plots the known concentration of the analyte standard versus the instrument response.

#### 7.1.18 Surrogates

Surrogates are organic compounds which are similar to the analytes of interest in chemical composition, but which are not normally found in samples. These compounds are spiked into all blanks, standards, samples, and spiked samples prior to analysis. Percent recoveries are calculated for each surrogate.

### 7.2 CALCULATIONS

This section describes various calculations which are frequently carried out to describe data quality.

#### 7.2.1 Precision

Precision from samples analyzed as duplicates is reported as relative percent difference (RPD). The RPD is calculated by

$$RPD = \frac{(C_1 - C_2) \times 100\%}{(C_1 + C_2) / 2}$$

where:

$C_1$  = the larger of the two values.

$C_2$  = the smaller of the two values.

From these data, a table of RPD values for various C values can be developed as an indication precision over different concentration ranges. This table can be used to set acceptance limits to duplicate results generated under the same conditions.

For data sets of three or more replicates, the standard deviation (SD) or relative standard deviation (RSD) is typically reported as the measure of precision. These values are calculated as

$$SD = \sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n - 1}}$$

where:

$n$  = number of replicates;

$x_i$  = a specified observed value;

$\bar{x}$  = the mean of the observed values.

$$RSD = \frac{SD \times 100\%}{\bar{x}}$$

When reporting precision, it is essential to include the nature of the replicate and the number (n) of replicates.

## 7.2.2 Accuracy

Accuracy is evaluated in part by measuring the recovery from spiked samples. Percent recovery (P) is given by

$$P = \frac{(Z - X) \times 100\%}{T}$$

where:

$Z$  = Measured concentration in spiked sample.

$X$  = Measured concentration in unspiked sample.

$T$  = Actual concentration for spike added.

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SRMs may also be used to calculate accuracy:

$$P = \frac{(C - T) \times 100\%}{T}$$

where:

C = The measured concentration.

T = The true concentration of analyte in the SRM standard.

### 7.2.3 Control Charts

Typically, fixed QC acceptance criteria (i.e., limits which must be met before analyses can proceed) are imposed on critical parameters. Alternatively, acceptance limits may be set through the use of control charts, in which the QC data (e.g., recovery from a spike-blank) may be recorded on a chart similar to that shown in Figure 7.1. Control limits of three standard deviations from the means (SD) are usually defined as the bounds between which most data must lie, and any data outside of this limit signify an analytical problem for which corrective steps must be taken. Other criteria requiring corrective action may be a set number of points between two and three standard deviations from the mean, or a given number of points trending in one direction. There are numerous methods for defining control limits with control charts, and a person familiar with statistics should be consulted regarding the best approach.

S-CUBED Division of Maxwell Laboratories											
Method _____											
Deviation From Mean	3σ	Action Item									
	2σ	Warning Limit									
	σ										
	Q										
	-σ										
	-2σ	Warning Limit									
	-3σ	Action Item									
Check No.	1	2	3	4	5	6	7	8	9	10	
Date/Time											
Operator											
Problem and Corrective Action											

Figure 7.1. Standard Quality Control Chart

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## 8.0 QA/QC TECHNICAL SUPPORT SERVICES

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In addition to the QA/QC effort associated with in-house measurement activities, S-CUBED provides technical QA/QC Technical Support Services on a contract basis to state and government agencies, as well as private concerns engaged in experimental design and data generation/collection activities. Established quality assurance procedures ensure the assignment of appropriate personnel to QA support projects and provide for several levels of review, assessment of findings, and recommendations before reporting. Figure 8.1 shows the generalized scheme for quality assurance on QA support projects.

### 8.1 SELECTION OF PROJECT TEAM

Each individual task associated with a QA support project requires the selection of expert professionals for participation on the project team. Availability and selection of appropriate experts is a most important aspect of QA support project management.

#### 8.1.1 QA/QC Audits

Several types of audits are performed by the S-CUBED QA/QC Technical Support Services group. These include: Performance Evaluation Audits (PEA), Technical Systems Audits (TSA), Management Systems Audits (MSA), and Audits of Data Quality (ADQ).

The PEA requires a team including analytical specialists experienced in the measurement systems being evaluated. The specialists may be scientists and/or engineers, depending upon the types of measurement systems. A statistician is involved in assessing the results of Performance Evaluation (PE) samples. Also, laboratory support personnel are required when S-CUBED produces and certifies PE samples. Production and certification of PE samples requires adherence to previously described QA/QC procedures for laboratory practices.

Similarly, the TSA requires analytical specialists for evaluation of measurement systems. In addition, a sampling procedure expert is sometimes involved. This person is usually drawn from the S-CUBED Environmental Engineering Program and has experience in planning, execution, and management of sampling efforts. A statistician may be required if the auditee is employing sophisticated procedures for the estimation of data quality parameters. Finally, a quality assurance professional, usually a scientist, is employed in assessing the auditee's project organization, implementation of QA programs, documentation and reporting protocols, and corrective action procedures.

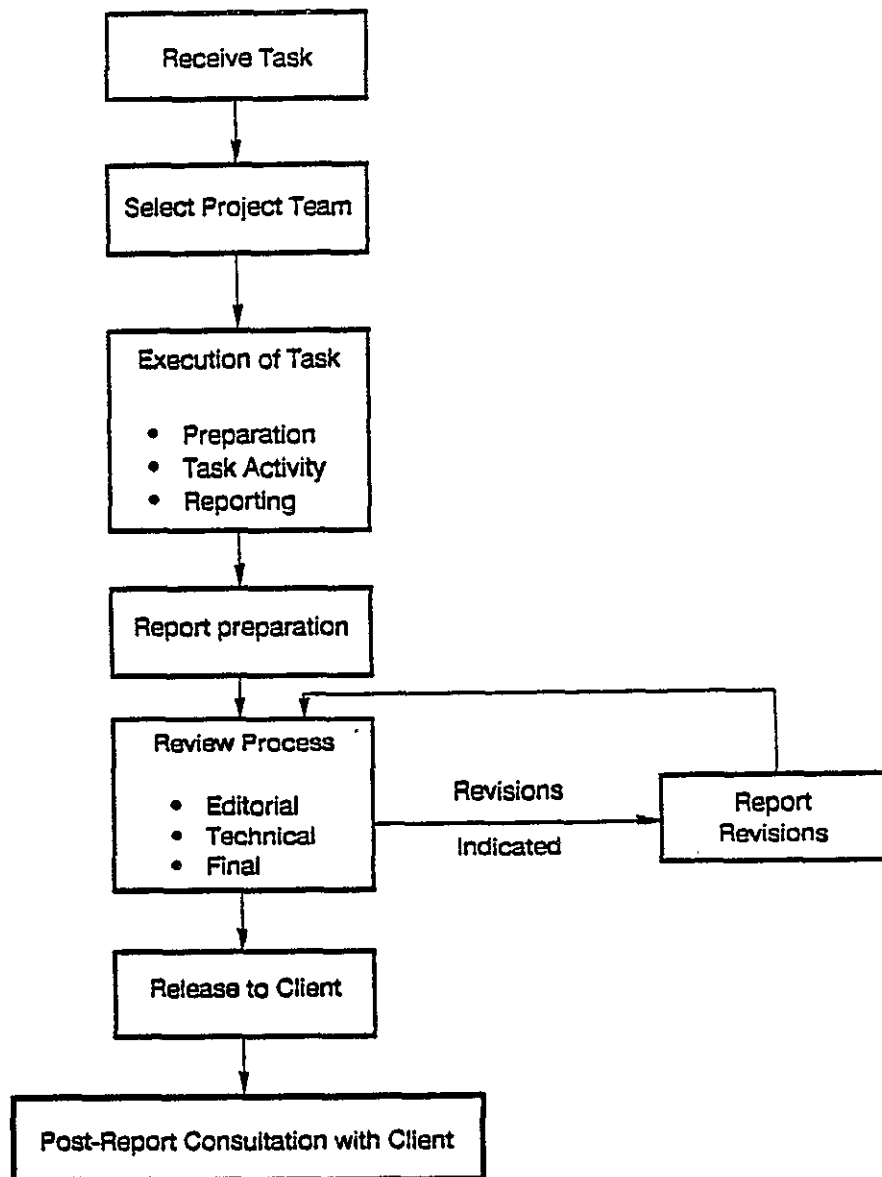


Figure 8.1. QA/QC Technical Support Services Project Scheme

The ADQ is an in-depth, sometimes lengthy examination of data quality produced from one or more measurement systems. The team is the same as that required for a TSA, but may require a more extensive commitment.

The MSA requires the participation of one or more quality assurance professionals in an on-site audit of the QA program. The audit concludes at S-CUBED with a review of documentation gathered from the on-site visit. Additional expertise is drawn, as needed, from S-CUBED's diverse group of scientists, engineers, and computer experts.

#### 8.1.2 Document Review

Several types of QA/QC documentation are reviewed and evaluated, including QA Program and Project Plans, Sampling and Analysis Plans, Experimental Designs, Statements of Work, and Final Reports. In each case, relevant specialists (scientists and engineers) are consulted by a quality assurance specialist. A written report is then produced by the quality assurance professional detailing the results of the review along with recommendations.

#### 8.1.3 Preparation of QA/QC Materials

QA/QC Material Preparation tasks require the involvement of technical experts with a quality assurance specialist. A statistician is required in the development of experimental design.

#### 8.1.4 Development of QA Methods

Relevant technical experts are consulted by the quality assurance specialist. The S-CUBED librarian is employed to provide literature searches in the initial phase of QA method development. After development, methods involving measurement and sampling activities are tested by the S-CUBED technical staff.

### 8.2 EXECUTION OF TASK

Necessarily, each QA/QC Technical Support Service task is of a specialized nature. Standard Operating Procedures are defined and submitted for approval prior to the initiation of work efforts. In general, tasks are undertaken in a three-phased approach:

- Preparation Phase - Available background documentation is reviewed and the project team is assembled and briefed. In the case of an audit, contact is made with the auditee. For a PEA, the PE sample and testing procedures are specified or designed.

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- Task Activity Phase - The actual on-site activities are conducted in the case of audits. For other types of tasks, documentation is assessed or actual experimental design work is pursued.
- Reporting Phase - A complete report is prepared detailing findings and activities. Appropriate review of the report is conducted.

Situations are sometimes encountered that require short response times for projects having severe or unusual schedule constraints. The S-CUBED quality assurance staff are skilled in responding effectively to such manpower-intensive assignments under QA/QC Technical Support Service contracts.

### 8.3 REPORT PREPARATION

After assembling and organizing all notes, comments, literature, and documentation, a report is produced by the Task Manager. Following completion of the report, a review process ensues which ensures the clarity, accuracy, and adequacy of the report.

- Editorial Review - A technical writer reviews the rough draft and checks for clarity, spelling, grammar, etc.
- Technical Review - The technical specialists involved in the task review the draft for accuracy and technical completeness.
- Quality Assurance Review - The S-CUBED Quality Assurance Manager reviews the report for adherence to QA requirements given in this section, as well as any project-specific requirements given in Work Plans, Statement of Work, or QA Project Plans.
- Final Review - The Project Manager reviews the report to ensure that the task requirements have been met and appropriate deliverable requirements have been satisfied.

Reviews are documented using the form shown in Figure 8.2. Following this review process, the report is bound and delivered to the client. The client will be contacted following submission of the report after a suitable period to determine the adequacy of the report and to determine whether clarification or revision is necessary.

<b>S-CUBED STANDARD REPORTS DOCUMENT REVIEW</b>	
1. TITLE:	
2. AUTHOR:	
3. S-CUBED PROJECT NUMBER:	
4. S-CUBED REPORT NUMBER:	
5. DATE DOCUMENT SHOULD LEAVE:	
6. TYPE OF DOCUMENT:	
Final: Topical Report: Journal Paper: Presentation: QA/QC Documentation:	Progress Report: - Monthly: Quarterly/Semiannual: Where/When:
7. DOES REPORT CONTAIN S-CUBED PROPRIETARY INFORMATION?	
8. CLASSIFICATION:	
Unclassified: Confidential: Secret:	
9. REVIEW:	NAME/DATE/INITIAL:
Author:	_____
Editorial Review:	_____
Technical Review:	_____
QA Review:	_____
Project Manager:	_____
Contracts:	_____

Figure 8.2. S-CUBED Standard Reports Document Review Form

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## 9.0 QA/QC FOR METHODS DEVELOPMENT

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Projects whose primary objectives are the development, demonstration, or validation of new or newly adapted methods of analysis for environmentally related samples, require specialized or intensified quality assurance and quality control measures in addition to those described in the chemical analysis sections of this document. Since each method development and validation task is unique, only a generic description of the quality assurance program associated with such tests can be presented in this Quality Assurance Program Plan. Method development at S-CUBED typically involves some or all of the following steps:

- Candidate methods review and selection, including literature reviews,
- Preparation and review of a written protocol,
- Development of validation criteria,
- Single-laboratory testing,
- Collaborative testing, and
- Final method evaluation.

Each of these steps is discussed in detail in the following subsections, with reference to the relevant QA/QC measures.

### 9.1 CANDIDATE METHODS REVIEW AND SELECTION

A general approach for the selection of appropriate candidate methods involving sample handling, preparation, and/or analysis is based on a critical review of techniques employed and the ability to conform to technical and regulatory requirements outlined in the Statement of Work. Literature reviews are conducted with the assistance of the S-CUBED full-time librarian and the in-house library. On-line library search data bases (e.g., Dialog) are employed, and the University of California (San Diego) technical library is also accessible. Figure 9.1 illustrates the general, organized approach used for literature reviews for methods development projects. Specific factors considered in this review typically include some or all of the following:

- Sample Collection - evaluation of sampling equipment, sample containers, and sampling techniques for matrix compatibility and applicability to the collection of samples having specific physical and chemical characteristics.

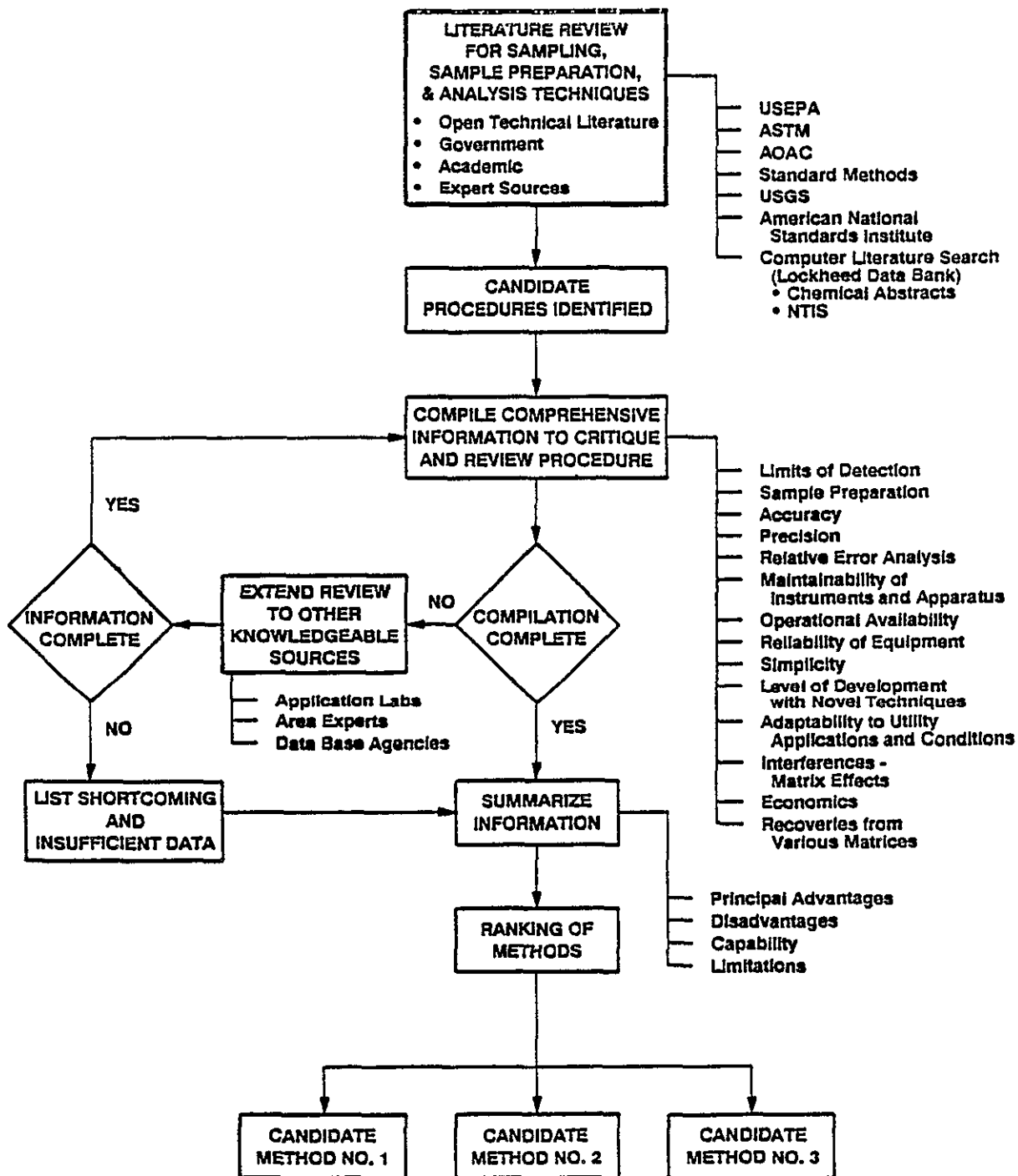


Figure 9.1. Literature Review Flow Chart for Methods Development

- Sample Preservation and Storage - evaluation of methods and reagents used for sample preservation and storage for their ability to maintain sample integrity and minimize sample contamination or degradation.
- Sample Preparation - evaluation of sample preparation techniques for efficiency, selectivity, speed, labor intensity, completeness, precision, accuracy, and ability to reduce or compensate for matrix interferences.
- Accuracy - examination of data on recovery of matrix spikes and QC standards, servicing of instruments, and certification of reagents and standards.
- Precision - evaluation of the repeatability of measurements made using the candidate analytical method.
- Limits of Detection - review of detection limit data and evaluation of method accuracy near the detection limit.
- Relative Error Analysis - examination of systematic errors related to the procedure, the analyst, and the instrumentation.
- Instrument Reliability and Maintenance - review of instrument type, construction, required maintenance frequency, and operational sources of instrument degradation.
- Automation and Throughput - evaluation of analytical methods for sample analysis time, throughput, and potential for programmable, unattended operation.
- Operational Availability - estimation of the ratio of instrument on-line to down times.
- Complexity - review of the number of procedural steps, level of difficulty, potential ambiguity, intricacy of instrumentation, and expertise of operation required.
- Interferences and Matrix Effects - evaluation of the method for potential interferences, carryover effects, and suitability for use on a variety of different, environmentally related matrix types.
- Economics - estimation of the costs associated with the instrumental requirements and labor specific to the performance of analyses.

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Quality assurance of the methods review and selection process consists of careful documentation of each of the factors involved and an independent review of the written reports detailing results of the review/selection process.

## 9.2 PREPARATION AND REVIEW OF A WRITTEN PROTOCOL

Once a candidate method has been selected for further evaluation, members of the project technical staff prepare a written method protocol suitable for testing with planned or existing facilities and equipment. Quality control of the protocol preparation process includes review by project management to ensure the incorporation of adequate quality control checks and to eliminate ambiguities and unnecessary complexity in the procedure. Quality assurance at this step may involve the independent verification that the quality control measures have been carried out and that copies of the protocol have been made available to the appropriate project personnel. Also, Dr. Arthur Carpenter, S-CUBED Statistician, aids in the experimental design and review of the method validation study.

## 9.3 DEVELOPMENT OF VALIDATION CRITERIA

During this stage of method development, a candidate method will typically undergo laboratory familiarization tests to identify the potentially critical method parameters to be varied for method optimization. At this time, other criteria external to the technical aspects of the method are also considered. These external criteria may include the intended scope of application, data quality requirements, practical considerations of time, cost, and skill requirements, or other factors deemed appropriate for defining the user's minimum requirements for a method.

Following the initial identification of critical method parameters and method validation criteria, some level of method optimization is usually required. For simple procedures, a linear variation of critical method parameters may be employed, but for procedures that involve many critical parameters, a nonlinear approach, such as the simple optimization methods defined by Morgan and Deming<sup>1</sup> and Legget<sup>2</sup> will often be required.

The list of method validation criteria is reviewed and typically revised at the completion of the optimization tests. The final list of validation criteria may include consideration of the following data quality indicators in addition to the minimum data quality objectives needed to meet or support the regulatory, strategic, or other user requirements:

- Within-laboratory precision,

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1. Morgan, S.L., Deming, S.N., *Anal. Chem.*, 1974, 46, 1170.

2. Legget, D.J., *J. Chem. Educ.*, 1983, 60, 707.

- Reproducibility among laboratories,
- Analyte recovery,
- Accuracy or method bias,
- Method sensitivity and limits of detection, and
- Assumptions regarding the statistical distribution of data.

Quality assurance during the development of validation criteria will entail (1) independent examination of familiarization and optimization data to ensure that appropriate procedures have been followed and results have been properly documented, (2) regular communication with S-CUBED project management and the EPA Project Officer to ensure that all user requirements are being taken into account, and (3) review of reports that present final validation criteria, optimization results, and revisions to the protocol, if any, to ensure correct and complete documentation.

#### 9.4 SINGLE-LABORATORY TESTING

Single-laboratory testing at S-CUBED is designed to evaluate the quality of measurement data that can be obtained in a single laboratory using the written method protocol. The results of single-laboratory testing are used to identify and quantify (1) the sources of significant variability in method performance, (2) probable systematic error, or method bias, (3) the usable dynamic range and limits of detection for method measurements, (4) method sensitivity, the ability of the method to respond to small changes in analyte concentration, and (5) method ruggedness, the relative stability of method performance for small variations in critical method parameter values.

Single-laboratory testing is typically conducted in five stages as follows:

- (1) Preliminary Method Evaluation;
- (2) Ruggedness Testing;
- (3) Method Range and Detection Limits;
- (4) Referee Validation;
- (5) Matrix Validation.

Each stage is discussed briefly in the following subsections.

##### 9.4.1 Preliminary Method Evaluation

Preliminary method evaluation tests a candidate method for its general performance characteristics, the presence of major technical difficulties, and the potential for successful optimization and application. When properly conducted, familiarization and optimization tests described in Sections 9.2 and 9.3,

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respectively, constitute an appropriate and complete preliminary method evaluation. As a result of this evaluation, unsuitable methods, whose performance characteristics fail to meet minimum validation criteria, may be screened out, thereby reducing the cost and time involved in overall methods development.

#### 9.4.2 Ruggedness Testing

Ruggedness testing is conducted on suitable candidate methods by systematically varying the identified critical method parameters and observing the performance sensitivity of the method to the variations introduced. S-CUBED employs appropriate standard ruggedness test protocols, such as those of Youden and Steiner,<sup>3</sup> Williams,<sup>4</sup> and Cole, Degner, Rust, and Warner,<sup>5</sup> to conduct all ruggedness tests for method development projects.

The results of ruggedness tests are used to specify appropriate performance limits for critical method parameters within which no statistically significant adverse effects on method performance are expected.

The quality control procedures described in Sections 5.0, 6.0, and 7.0 of this document are intensified during the ruggedness testing stage of method development. Multiple spiked blanks at a minimum of three concentration levels are routinely employed to probe the effects of critical parameter variation. Evaluations of the variations of critical parameters on method response are conducted using statistical procedures called out in the particular ruggedness test procedure and include tests for outliers and the calculation of means, standard deviations, and t-tests of significance. Ruggedness tests also typically require statistical evaluations of results for a minimum of two ranges of variation for the critical method parameters, to provide estimates of the degree of method performance sensitivity to variations in each parameter and to define the limits of acceptable performance for each parameter.

Quality assurance for ruggedness testing involves the critical review of all laboratory procedures, notebooks, and logs, and of all data reports, to ensure that correct procedures have been closely followed and that all measurement data and calculated results are properly documented.

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3. Youden, W.J., Steiner, E.H., *"Statistical Manual of the Association of Official Analytical Chemists,"* AOAC, Arlington, VA, 1975.
  4. *"Validation of Testing/Measurement Methods,"* EPA 600/X-83-060, by Llewellyn R. Williams, Environmental Monitoring Systems Laboratory, Las Vegas, NV, U.S. Environmental Protection Agency, September 1983.
  5. Cole, T.F., Degner, K.B., Rust, S.W., Warner, J.S., *"Single-Laboratory Method Validation Protocol,"* prepared for U.S. Environmental Protection Agency, Environmental Monitoring Systems Laboratory, Cincinnati, Ohio, under EPA Contract No. 68-03-3224, September 6, 1985  
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#### 9.4.3 Method Range and Detection Limits

During this stage of method validation, the concentration range over which the method is sufficiently reliable, precise, and accurate is determined for each method analyte. The method detection limit (MDL) will also be determined for each analyte at a 99 percent level of confidence that the concentration of the analyte is greater than zero.

The level of quality control for range and MDL determinations is similar to that for ruggedness testing. Multiple spiked blanks at a minimum of five concentration levels are analyzed in random order by the candidate method. The resulting data are tested for outliers and are statistically evaluated according to the specifications of the test procedure, which includes the calculation of means, standard deviations, and levels of confidence, and which stipulates appropriate means for the generation and use of evaluation criteria for the results.

Data from this stage of method development is also used to determine the limits of method precision and recovery for each method analyte. The equations for these determinations are specified in the testing methods and include those given in Section 7.0 of this document.

Quality assurance for method range, detection limits, precision, and recovery follows that described in Section 9.4.2 for ruggedness testing.

#### 9.4.4 Referee Validation

In referee validation, an experienced analyst not otherwise involved in the method development effort performs the entire method protocol on a set of replicate spiked blanks and Internal Reference Material, using equipment not otherwise employed in the method development project. Referee data are evaluated for method precision and accuracy, and the results are compared with similar data obtained by the method development team and with the method performance requirements. Referee validation tests the repeatability of the method and the clarity and correctness of the written protocol.

Quality assurance for referee validation involves the critical review of all laboratory procedures, notebooks, and logs, and of all data reports, to ensure that correct procedures have been closely followed and that all measurement data and calculated results are properly documented.

#### 9.4.5 Matrix Validation

The final stage of single-laboratory testing involves the acquisition and demonstrative analysis of a minimum of two relevant environmental samples spiked with known quantities of method analytes at a

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minimum of two concentrations spanning the method range. The results of matrix validation are used to evaluate method precision, accuracy, and range for the representative environmental matrices.

Quality control and quality assurance measures for matrix validation are the same as those specified in Section 9.4.3 for method range and MDL.

## 9.5 INTERLABORATORY COLLABORATIVE TESTING

Collaborative testing programs managed by S-CUBED are designed to evaluate the analytical data quality and overall performance characteristics of a method as performed by a specified number (but no fewer than six) of independent, qualified laboratories. Because of their magnitude and cost-intensiveness, collaborative studies are usually only performed on methods which have been validated in single-laboratory tests and which demonstrate a reasonable likelihood of success in the proposed multilaboratory testing program. Preliminary considerations for collaborative study design include (1) careful selection of qualified laboratories, (2) comprehensive definition of all test variables, including method analytes, test sample matrices, test schedules, and data reporting criteria, (3) specification of the statistical analysis techniques used to analyze the data, (4) definition of the criteria used in the analysis and interpretation of the data, and (5) specification of reporting criteria and parameters to be used in the final report. S-CUBED employs standard guidelines, such as those of Youden and Steiner<sup>3</sup> and Williams<sup>4</sup> (loc. cit., Section 9.4) in the design and execution of all interlaboratory collaborative testing programs.

Quality control for collaborative testing programs begins with a thorough specification and faithful implementation of the quality control measures described in the method protocol. These measures typically include, but are not limited to, the measures described in Section 5.4.2 of this document. In addition to these, the quality control measures described in Section 5.3 of this document must be implemented during the preparation and distribution of all test samples. Finally, quality control in collaborative studies requires that each participating laboratory analyze the requisite numbers and types of blind samples (e.g., blind duplicates, Youden<sup>3</sup> pairs, etc.) needed to support the statistical techniques used to analyze the data.

Quality assurance for interlaboratory collaborative testing is extensive and can involve some or all of the following activities:

- Preliminary and ongoing QA audits of participating laboratories;
- Preparation, review, and approval of a detailed QA Project Plan;

- Scheduled periodic oral and written communications between the technical and QA/QC coordinators for the participating laboratories and the S-CUBED Program Manager and QAM;
- Critical review of all data reports to ensure correct and complete documentation of results;
- Expert consultation on matters relating to the correct application of statistical techniques and the interpretation of the results; and
- Preparation and review of a comprehensive final report which includes all QA/QC results in a separate, well-defined section.

S-CUBED retains the expert services of Dr. Ivan Show in matters relating to the application of statistical techniques to method validation and evaluation data.

Data quality assessment procedures for collaborative studies include considerations of the following statistical techniques:

- Within-laboratory assessments of precision and recovery;
- Between-laboratory assessments of reproducibility;
- Outlier identification and treatment using the Dixon criterion;
- The two-way ranking test of Youden and Steiner<sup>3</sup> for participating laboratories;
- Data clustering techniques;
- t-Statistic tests of significance;
- Two-parameter F-statistic tests for systematic errors; and
- Analysis of Variance (ANOVA).

Specific applications of these data assessment techniques are defined in the referenced guidelines<sup>3,4</sup> (loc. cit., Section 9.4) for collaborative test program design.

## 9.6 FINAL METHOD EVALUATION

Final evaluations of developed methods which have undergone single- and multi-laboratory testing is typically the responsibility of the Agency office sponsoring the method development effort. S-CUBED supports the final evaluation efforts with (1) preparation of a complete information package that contains all single-laboratory and collaborative test data and results for methods developed by or under the direct management of S-CUBED, (2) critical review of, and informed commentary on, reports of

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such tests conducted by other organizations under Agency sponsorship, and (3) audits of data quality for such tests conducted by such other organizations.

## 10.0 CORRECTIVE ACTION

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Quality assurance criteria presented in previous sections of this document are specifically designed to preclude the need for corrective action. Exacting personnel requirements, rigid facilities, equipment, and services controls, careful attention to data generation, data processing, and data quality assessment all combine together to form a comprehensive quality assurance protocol designed to minimize the need for corrective action. It is true, nevertheless, that each of the above-cited quality assurance parameters also contain, as integral parts of their structure, specifically defined feedback systems designed to indicate clearly those occasions when generated data fall below acceptable quality limits.

In those instances where corrective action is found to be necessary based on quality of acquired data, the Project Plan shall identify areas of responsibility for taking corrective actions as needed. Both internal and external S-CUBED project activities must delineate management responsibility for the delegation of corrective action as well as provide a defined feedback system specifying which personnel took the corrective action and when such action was taken. All correction activities must result in the reestablishment of data generation within acceptable quality limits, return to in-control conditions, or correction of the quality problem. Such corrections must be documented by the initiating individual.

All corrective actions taken during the course of a project, as well as any changes in procedure or loss of data resulting from such actions, will be communicated to the Quality Assurance Manager. This closed-loop feedback will ensure that appropriate levels of QA are maintained and updated wherever necessary during the course of all S-CUBED projects.

Individual corrective actions relative to ongoing project activities may be implemented automatically as a result of information derived from the activity or corrective action may also result from any of the following parameters:

- (1) Performance audits,
- (2) Systems audits,
- (3) Interlaboratory/interfield comparison studies,
- (4) Failure to adhere to a QA Program or Project Plan, or to standard procedures, and
- (5) Other significant observations of the QA system (facilities, equipment, personnel, procedures, QC data, control charts, etc.).

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*APPENDIX A*  
*STANDARD OPERATING PROCEDURE FOR WRITING STANDARD OPERATING PROCEDURES*

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Standard Operating Procedure  
for  
Writing Standard Operating Procedures

1.0 PURPOSE

The purpose of this procedure is to describe the content and organization of Standard Operating Procedures (SOPs). The procedure describes the common format and numbering System to be used in writing SOPs, the review and approval Process and the distribution, revision and storage of SOPs.

2.0 APPLICATION

This procedure applies to all routine laboratory activities. Each method, technique, and quality control procedure as performed in the S-CUBED Chemistry Group is documented in the form of an SOP.

3.0 CONTENTS

3.1 All SOPs will normally contain the following sections. Writers are encouraged to follow the format listed below:

- Section 1 - Purpose

States the reason for writing the SOP.

- Section 2 - Application

Describes the sample type, matrix, project or policy to which the SOP pertains. Includes any relevant limitations and exclusions such as the applicable range of concentrations.

- Section 3 - References

Lists any documents used in writing the SOP, such as instrument manuals, and published methods. Any applicable NIOSH, SW-846, or CLP IFB procedures must be referenced.

- Section 4 - Scientific Basis

Describes the chemical and analytical principles applicable to the method.

- Section 5 - Associated SOPs

Refers to other SOPs that are directly related to the current SOP.

- Section 6 - Safety

Discusses any particular hazards, safety techniques or cautionary statements specific to the method. Reference material safety data sheets as needed.

- Section 7 - Apparatus

Lists all instrumentation, equipment, glassware, chemicals, reagents, and preparation procedures.

Subsection 7.1 - Instruments

Subsection 7.2 - Hardware/glassware

Subsection 7.3 - Chemicals, reference materials, and standards obtained from outside S-CUBED.

Subsection 7.4 - Reagent preparation procedures

- Section 8 - Calibration and QC Standards

Contains methods of preparation of any necessary standard solutions used for system calibration or method QC (may reference an applicable SOP).

- Section 9 - Instrument Parameters

Includes relevant control settings. Must include references to instrument manuals when applicable.

- Section 10 - Procedures

A step-by-step description of the activity. This section should contain sufficient detail that a person familiar with the principles involved should be able to perform the activity by referring to the procedure. This does not preclude the necessity for a training program for more junior employees. This section includes calibration requirements, run sequence, specifications, etc.

- Section 11 - Calculations

The applicable calculations are described and the formulas and equations are provided. Include calculations of quality assurance parameters such as method accuracy and precision in this section.

- Section 12 - Quality Control

Includes a list and discussion of applicable QC samples and their frequency. This section describes the QC criteria that must be met before data are reported and the appropriate corrective action if those criteria are not met.

- Section 13 - Supplementary Notes

Includes any information not otherwise described in the SOP (e.g., recommendations pertaining to using a particular device, or preparation of difficult matrices).

3.2 The top right-hand corner of each page of an SOP shall contain the following information:

SOP No:  
Date Initiated:  
Date Revised:  
Page \_\_\_\_ of \_\_\_\_.

3.3 Attached to each SOP is an approval page signed and dated by the author, the Chemistry Program Manager, and the Quality Assurance Manager.

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#### 4.0 NUMBERING OF SOPs

Each SOP shall be assigned a unique number by the Quality Assurance Manager. The SOPs will be numbered as follows:

00	-	001	-	00
Section		SOP No.		Revision No.

The first two digits are the section number and represent the activity for which the SOP is applicable. The middle three-digit number is the unique SOP identification number. SOPs will be numbered consecutively from 001 as they are approved by the Quality Assurance Manager. The last two-digit number is the revision number for the particular SOP. Revision 00 is the original version of each SOP.

The following section numbers will be used in SOP numbering in the S-CUBED Chemistry Group:

- 00 Miscellaneous
- 10 Safety
- 20 Quality Control
- 30 Sampling
- 40 Sample Preparation
  - 41 Organic Prep
  - 42 Inorganic Prep
  - 45 Leaching Techniques
- 50 Organic Analysis
  - 51 VOA GC/MS
  - 52 GC/MS (semivolatiles)
  - 53 HPLC/MS
  - 54 VOA GC
  - 55 GC/Selective Detector (semivolatile)
  - 56 Other GC
  - 57 HPLC
  - 58 Screening Procedures
  - 59 Spectroscopic Analysis
- 60 Inorganic Analysis
  - 61 Flame AA
  - 62 Furnace AA
  - 63 ICP

- 64 ICP/MS
- 65 Ion Chromatography
- 67 Wet Chemistry
- 70 Miscellaneous Analysis
- 71 Physical Parameters
- 73 Biological Parameters
- 80 Laboratory Management
- 90 Calculations/Data Reporting

#### 5.0 AUTHORSHIP AND REVIEW OF SOPs

An SOP may be written by any qualified person; each SOP and any subsequent revisions shall be reviewed by the Chemistry Program Manager and a Quality Assurance Manager.

#### 6.0 CURRENCY OF SOPs

The Laboratory Section Supervisors are responsible for maintaining current copies of all applicable procedures in all areas for which they are responsible. Supervisors must review all SOPs annually (at a minimum) to ensure that there is no need for revision. A Continuing Approval/Termination Form will be attached to each SOP.

#### 7.0 SUPERSEDED SOPs

Supervisors shall ensure that all personnel are using the most current SOPs. All superseded SOPs must be removed from the work area.

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Example of Continuing Approval/Termination Form

Effective Date: \_\_\_\_\_ Date Discontinued \_\_\_\_\_

Signatures

Date

Author: \_\_\_\_\_

Supervisor: \_\_\_\_\_

QA: \_\_\_\_\_

Reviewed